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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,031	06/07/2006	Karl Malcolm	02911.007800.	4013
5514 7590 04/13/2011 FITZPATRICK CELLA HARPER & SCINTO 1290 Avenue of the Americas NEW YORK, NY 10104-3800				
EXAMINER				
AL-AWADI, DANAH J				
ART UNIT		PAPER NUMBER		
1615				
MAIL DATE		DELIVERY MODE		
04/13/2011		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/564,031

Applicant(s)

MALCOLM ET AL.

Examiner

DANAH AL-AWADI

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 6-16, 19, 20 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 6-16, 19, 20 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Correspondence Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of Applicant's amendments and remarks filed 01/19/2011. The Examiner acknowledges the following:

Claims 1, 3, 6-16, 19, 20, and 22-24 have been amended.

Claim 25 is new.

Newly submitted claim 25 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: New claim 25 depends from the method of claim 22. The method of claim 22 is directed to a method of delivery a drug delivery device via administering a intravaginal drug delivery device into a vaginal environment.

New claim 25, while it recites it depends on claim 22, the steps appear to be directed to a method of manufacturing a drug delivery device.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 25 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statement (IDS) has been submitted for review.

WITHDRAWN REJECTIONS

Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Correspondence dated 30 March 2010:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 6-16, 19-20, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zaffaroni US Patent 3, 993,072, Chappaz et al. US Patent 2, 962, 023, and Saleh et al. US Patent 5, 972, 372.

With respect to claim 1, Zaffaroni discloses in Example 1, an implant device comprising at least one reservoir, the at least one reservoir containing at least one pharmacologically active agent (progesterone) or a prodrug thereof, dispersed in a hydrophobic elastomeric polymer (polydimethylsiloxane), and a porous sheath (wall) that surrounds the at least one reservoir, wherein the implant device is an intravaginal drug delivery device for administration into a vaginal environment (Examples 16 and 18; col. 23, lines 37-38; col. 24, lines 17-20). Zaffaroni further discloses the pore structure of the sheath (wall) further includes continuous pores, wherein a pore has an opening on both faces of the sheath connected therethrough thereby forming continuous diffusional paths (col. 10, lines 39-49). Therefore, the sheath is considered to discontinuously surround the at least one reservoir so as to define at least one hole or opening,

the at least one hole or opening extending through the sheath to the at least one reservoir, so that, in use, at least part of the at least one reservoir is directly exposed to the vaginal environment.

Zaffaroni does not explicitly disclose that the hole or opening has a diameter range of 0.5 to 6.5 mm and that the total surface area of the reservoir exposed to the vaginal environment through the one or more holes or openings, when in use, is in a range of 1 to 750mm², however Zaffaroni does teach that the rate of passage of drug through the media in the microporous wall material is generally dependent, in the case of diffusion, on the solubility of the drug in the media, as well as on the diffusion coefficient and on the size of the pores and the porosity and tortuosity of the material. Furthermore, Zaffaroni teaches that the pore structure can be substantially cylindrical. It would have been prima facie obvious to one of ordinary skill in the art to optimize the diameter of the hole or opening. One would have been motivated to do so because Zaffaroni teaches that the rate of passage of drug through the media in the microporous wall is dependent on the size of the pores (Col. 8. lines 55-63 and Col. 9 lines 31-36).

Although there is not an explicit teaching of the holes or openings having a diameter of 0.5 to 6.5mm, Chappaz et al. discloses in Fig. 2, a cylindrical intravaginal drug delivery device for use in a vaginal cavity, having at least one hole or opening at each of the terminal ends and additional holes or openings provided extending substantially radially through the sheath (10). Chappaz et al. teaches the diffusion rate and the amount of drug that is to be dispensed from the reservoir is dependent on the number of holes in the sheath (col. 1, lines 36-42). Chappaz et al. discloses in Figs. 1, an intravaginal drug delivery device having a plurality of holes that are substantially cylindrical (round hole which inherently has a depth through a sheath). Chappaz et

al. further teaches the holes are 1/32 inch in diameter, therefore is within the claimed diameter range (col. 4, lines 5-8).

It would have been obvious to one of ordinary skill in the art to modify the shape and size of the at least one hole or opening in order to further modify the desired diffusion rate of the drug from the reservoir, or to further modify the amount of drug to be dispensed. Further, a change in size and shape is generally recognized as being within the level of one of ordinary skill in the art. In re Rose, 105 USPQ 237(CCPA 1955); In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

Furthermore, regarding the limitation(s) “wherein each hole or opening is substantially cylindrical with a diameter in the range of about 0.5 to 6.5mm and the total surface area of the reservoir exposed to the vaginal environment through the one or more holes or openings, when in use, is in a range of 1 to 750 mm²”; absent evidence of criticality, since the values of each parameter with respect to the claimed composition are adjustable, it would have been prima facie obvious for a person having ordinary skill in the art to routinely optimize the amount of each parameter in the composition and adjust the diameter ranges and surface area of the reservoir.

Saleh et al. is relied upon to teach a polymer impregnated with drug that goes inside the outer sheath with holes. Saleh et al. discloses a vaginal ring containing a reservoir containing at least one pharmacologically active agent or prodrug thereof, dispersed in a hydrophobic elastomeric polymer (abstract, Fig. 4A-C and 5, col. 6, lines 46-57, Examples 2-7).

Saleh et al. demonstrates the hydrophobic elastomeric polymer as being polydimethylsiloxane (Examples 2-7).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the vaginal ring with holes as taught by Zaffaroni to include the core with the polymer and drug impregnated within the polymer that goes into the outer sheath with holes. One would have been motivated to do so in order to modify the diffusion rate of the drug from the reservoir as taught by Saleh et al. (col. 1 lines 35-42).

Additionally, it would have been obvious to one of ordinary skill in the art to modify the total surface area of the reservoir exposed to the vaginal environment through the one or more holes or openings, for the same purpose (i.e. in order to further modify the desired diffusion rate of the drug from the reservoir as taught by Saleh et al. (col. 1 lines 35-42)).

With respect to claim 3, Zaffaroni discloses the at least one hole or opening is on both faces of the sheath (wall) and is connected therethrough, therefore is considered to extend to the surface of the at least one reservoir and/or extends partially into the at least one reservoir (col. 10, lines 39-42).

With respect to claim 6, Zaffaroni discloses the continuous pores, such as straight continuous pores, has the at least one hole or opening is on both faces of the sheath (wall) and is connected therethrough and forms a diffusional path for passage through the sheath (col. 10, lines 39-49), therefore is considered to extend through the sheath substantially normal to the reservoir surface. The examiner interprets the continuous pores to be openings extending through the sheath (wall) to at least one reservoir.

With respect to claim 7, Zaffaroni discloses in Fig. 8, the device is a ring that is substantially circular in transverse cross-section, and the sheath has a multiple micropores

formed with continuous diffusional paths through the sheath (col. 24, lines 20-22). Zaffaroni further describes the pore structure of the sheath having continuous pores, where each pore has an opening on both faces of the sheath (wall) and is connected therethrough (col. 10, lines 39-42). Therefore, the examiner interprets the at least one hole (continuous pore/continuous diffusional path) extends substantially radially through the sheath at the inner circumference of the ring or at the outer circumference of the ring.

With respect to claim 8, Zaffaroni addresses all the limitations of claim 7, and further discloses multiple pores formed with continuous diffusional paths (continuous pores with openings) along the inner or outer circumference of the intravaginal drug delivery device (col. 24, lines 17-23).

However, Zaffaroni fails to expressly disclose the exact number of holes or openings. Zaffaroni further teaches the porosity affects the diffusion rate of the drug through the media in the wall (col. 9, lines 31-36).

Therefore, it would have been obvious to one of ordinary skill in the art to modify the number of holes or openings in the inner or outer circumference of the intravaginal drug delivery device in order to attain the desired diffusion rate.

With respect to claim 13, Zaffaroni discloses in Example 18, the device is a ring (toroid shape).

With respect to claim 16, Zaffaroni doesn't disclose that the sheath comprises at least one additional pharmacologically active agent, however Saleh et al. discloses a sheath that comprises at least one additionally pharmacologically active agent (col. 6 lines 33-36; col 7 lines 42-46).

It would have been prima facie obvious to one of ordinary skill in the art to further have the sheath comprise one additional active agent to obtain additional release of a drug.

With regards to the limitations “wherein the sheath is impermeable to the at least one pharmaceutically active agent or the prodrug thereof and wherein the at least one pharmaceutically active agent or prodrug thereof is released from the hydrophobic elastomeric polymer of the at least one reservoir through the surface area of the reservoir that is exposed to the vaginal environment”, Zaffaroni discloses a sheath (wall) that is impermeable to the drug. Furthermore, it is obvious that the sheath would be impermeable to the drug to provide for controlled release. Furthermore, the combination of Zaffaroni and Saleh would provide for the drug released from the hydrophilic elastomeric polymer as taught by Saleh.

With regards to new pending claim 19, Zaffaroni teaches delivery of drugs in the order of micrograms which would be a certain dosage of milligrams per day (Examples 1 and 15).

With regards to the new limitation that the drug delivery device is capable of delivering relatively hydrophilic and/or relatively large molecular size/volume/weight drugs at a pharmaceutically suitable rate, Zaffaroni teaches delivery of progesterone which is hydrophilic.

Regarding new claims 22-24, these do not add any other structural limitations but are merely methods of delivering large molecular size/volume/weight drugs at a pharmaceutically suitable rate from and intravaginal drug delivery device comprising administering the drug delivery device into a vaginal environment. The drug delivery device has been obviated by the combination of Zaffaroni, Saleh, and Chappaz as discussed supra and the device is administered to a vaginal environment.

RESPONSE TO ARGUMENTS

Applicant's remarks with regards to Zaffaroni have been fully considered and are not persuasive. Applicant argues that Zaffaroni use the term "drug delivery device" to embrace several types of devices and that those skilled in the art would have understood that not specifying vaginal delivery as an option in Example 1 indicates that it is not necessarily suitable for that purpose, bearing in mind the wide range of drug delivery devices taught by Zaffaroni.

In response to applicant's remarks, the Examiner respectfully submits that Example 1 of Zaffaroni states a drug delivery device. Merely not specifying that the device is an intravaginal ring does not preclude the device from including an intravaginal ring. Zaffaroni states that the drawings are examples of various drug delivery devices of the invention (i.e., as in Fig. 8 the vaginal ring) and are not to be construed as limiting. Zaffaroni states that the drug delivery devices can take a wide variety of sizes and forms for administering the drug at controlled rates to different areas of the body. It is reasonable to assume that Example 1 can broadly include any of the drug delivery devices as disclosed by Zaffaroni which could also include the vaginal ring. Example 1 does not exclude the device being a vaginal ring.

Applicants further argue that Example 1 of Zaffaroni teaches progesterone which has a molecular weight of 314.5 Daltons, whilst the presently amended claims require the drug have a molecular weight greater than 400 Daltons.

In response, the Examiner respectfully submits that Zaffaroni teaches drugs such as progesterone with a lower molecular weight as claimed, however Zaffaroni does not exclude drugs having higher molecular weights from being used in the drug delivery devices of the

invention as taught by Zaffaroni that a wide variety of drugs are suitable for use in the invention of Zaffaroni. These are not limited to drugs with molecular weights lower than 400 Daltons. For example, Zaffaroni discloses use of drugs such as anti-microbials such as tetracycline which has a molar mass of 444.435 g/mol. Zaffaroni specifically states that the term “drug broadly includes physiologically or pharmacologically active substances for producing a localized or systemic effect or effects in mammals including humans and primates...The active drugs that can be administered by the drug delivery devices of the invention include, without limitation for example...” higher molecular weight substances such as the tetracycline (column 18 line 51). Therefore, Zaffaroni does disclose having molecular weight drugs higher than 400 Daltons for use in the drug delivery device. This limitation is given little weight anyway since it is well within the ordinary level of skill in the art to select whichever medication is to be given and drugs of similar or larger molecular weights would be expected to be released similarly, absent a showing of evidence to the contrary.

Applicants further state that as to claims 19 and 24, Zaffaroni teaches a uterine release of 10 to 200ug per day of progesterone and that Zaffaroni neither discloses nor suggest an intravaginal drug delivery device having a daily release rate of the drug in the order of milligrams per day.

In response, the Examiner respectfully submits that Zaffaroni does disclose in general drug delivery devices which include intravaginal drug delivery devices as discussed supra, and Zaffaroni teaches these drug delivery devices can deliver drugs in milligrams over a period of 24 hours. Applicant has not claimed a specific amount of drug delivered per day. Zaffaroni's discloser of 10 to 200ug/day would read on having an amount of 0.01mg/day to 0.2mg/day.

Zaffaroni states that an example of drug release of the drug delivery device can include milligram amounts where for example, 15 to 30 mg of a drug is released over a 24 hour period. Although Zaffaroni discloses ug/day of the progesterone, this is equivalent to having 0.01mg/day to 0.2mg/day.

Applicants further argue that Zaffaroni teaches "at column 2, lines 19-41, that many important drugs, including progesterone, diffuse quickly through a polydimethylsiloxane sheath, so much that diffusion through the sheath is not the rate-limiting step. Accordingly, Zaffaroni teaches that polydimethylsiloxane sheaths, being hydrophobic elastomeric sheaths, are disadvantageous, thereby teaching away from the present invention.

In response, the Examiner respectfully submits that column 2, lines 19-41 of Zaffaroni is not stating the disadvantages of having polydimethylsiloxane sheaths, but rather Zaffaroni teaches the importance of the consideration of release rate controlling properties.

Furthermore, with regards to a polydimethylsiloxane sheath, applicants are arguing limitations not found in the claims. The claims recite hydrophobic sheath. Zaffaroni teaches this limitation (i.e. wall). The microporous wall can be made of hydrophobic materials (i.e. porous polysulfones).

With regards to Zaffaroni, applicants lastly argue that Zaffaroni fails to teach or suggest using pores with a diameter in the range of 0.5 to 6.5 mm as presently claimed.

In response, Examiner respectfully submits that Zaffaroni teaches that by varying pore diameter or porosity of the microporous material, substantial changes in drug release rate can be brought about while still using the same materials.

It is acknowledged by the Examiner that Zaffaroi did not teach the claimed pore diameter, however the Examiner alleged that it would have been obvious to one of ordinary skill in the art to combine Chappaz with Zaffaroni.

Applicants argue that Chappaz, like Zaffaroni does not teach or suggest delivery of a drug having a molecular weight greater than 400 Daltons at a pharmaceutically suitable rate. “Chappaz achieves drug delivery without requiring the drug to diffuse through the reservoir. In the devices of Chappaz, the entire core (drug and reservoir) is released through holes in an applicator. This is in contrast to the present application, wherein the reservoir comprises the hydroponic elastomeric polymer, in which the drug is dispersed, remains intact and in place. In the present invention, only the drug is released into the vaginal environment.”

In response, the Examiner respectfully submits that Zaffaroni does disclose using drugs that have molecular weights greater than 400 Daltons as addressed supra.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The structural features of the claims having only the drug released into the vaginal environment was addressed by Zaffaroni. Zaffaroni and Chappaz both recognize that the diffusion rate and the amount of drug dispensed from the reservoir are correlated to the holes in the sheath.

Chappaz teaches devices for the same use (i.e. intravaginal drug delivery) which also has holes or openings which overlap with those claimed. It would have been obvious to one of

ordinary skill in the art at the time the invention was made to modify the size and shape of the hole or openings in order to further modify the desired diffusion rate of the drug from the reservoir, or to further modify the amount of drug to be dispensed. A change in size or shape is generally recognized as being within the level of one of ordinary skill in the art. In *re Rose*, 105 USPQ 237 (CCPA 1955); In *re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing “(1) [t]hat the prior art taught away from the claimed invention...or (2) that there are new and unexpected results relative to the prior art.” *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004). *Zaffaroni* teaches that the object of the invention is to provide a device for the administration of locally or systemically acting drugs to produce a physiological or pharmacologic effect which device overcomes the aforesaid disadvantages (i.e. column 2, lines 19-41) of the prior art devices. Further *Zaffaroni* does not appear to be teaching away from using polydimethylsiloxane sheaths altogether, but teaching that the prior art devices have been based on the use of a single material as the diffusion control membrane. *Zaffaroni* teaches the importance of the consideration of release rate controlling properties.

Applicants further argue that *Saleh* teaches away from having its core exposed to the vaginal environment due to the fact *Saleh* is concerned with reducing initial burst of drug release from the core which is inconsistent with directly exposing the core to the vaginal environment.

Applicants also argue that the vaginal ring body of *Saleh* does not comprise a reservoir containing at least one drug dispersed in a hydrophobic elastomeric polymer and hydrophobic elastomeric sheath discontinuously surrounding the reservoir.

This argument has been fully considered and is not persuasive because Saleh teaches in embodiments where initial drug burst is not a problem, (i.e. can have a initial burst) the core may be vulcanized in situ in the ring body subsequent to its introduction into the channel (column 4 line 21). Saleh teaches that the core may be vulcanized in situ in the ring body, depending upon whether the drug is one in which the initial burst is to be avoided. Saleh suggests that for certain drugs the initial burst does not appear to be a problem. Saleh also suggests that the dimensions of the core are determined on the basis of factors such as the amount of drug to be delivered to the subject, the time over which the drug is to be delivered to the subject, the diffusion characteristics of the drug, and by the relative ease with which complimentary-sized channels can be formed in the support. Saleh also teaches that “in another preferred embodiment, vulcanization of the cores is performed after the introduction of the drug into the hollow channel of the ring body. This embodiment is employed when an initial burst of the drug does not cause undesirable side effects”(column 8 lines 15-18). The Examiner respectfully submits that “a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).” Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In *re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). In response to applicant’s arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicants also argue that the

vaginal ring body of Saleh does not comprise a reservoir containing at least one drug dispersed in a hydrophobic elastomeric polymer and hydrophobic elastomeric sheath discontinuously surrounding the reservoir, however the rejection was relied upon based on the combination of Zaffaroni, Chappaz, and Saleh.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danah Al-awadi whose telephone number is (571) 270-7668. The examiner can normally be reached on 9:00 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DA/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615